

CLAIMS

1. An agent for reducing side effects of diclofenac or a salt thereof, which comprises ornoprostil as the active ingredient.
2. The agent for reducing side effects according to claim 1, wherein the side effects are digestive disorders.
3. The agent for reducing side effects according to claim 1, which is a combination agent comprising an effective amount of ornoprostil and an effective amount of diclofenac or a salt thereof.
4. The agent for reducing side effects according to claim 3, wherein the effective amount of ornoprostil is a biological catalytic amount.
5. The agent for reducing side effects according to claim 4, wherein the biological catalytic amount of ornoprostil is from 1/100,000 to 1/1,000 based on 1 part by weight of diclofenac or a salt thereof.
6. The agent for reducing side effects according to claim 3, which comprises about 25 mg of diclofenac sodium and about 5 μ g of ornoprostil.
7. The agent for reducing side effects according to claim 3, which is a single solid preparation which comprises at least one small soft capsule preparation (A) comprising ornoprostil and an oily solution base, and a pharmaceutical composition (D-1) comprising diclofenac or a salt thereof and an excipient.

8. The agent for reducing side effects according to claim 7, wherein the solid preparation is a hard capsule preparation.

9. The agent for reducing side effects according to claim 8, which comprises from 40 to 95% by weight of the oily solution base based on 100% by weight of the small soft capsule preparation (A), and from 20 to 95% by weight of the excipient based on 100% by weight of the pharmaceutical composition (D-1).

10. The agent for reducing side effects according to claim 8, wherein the number of the small soft capsule preparation (A) is from 1 to 400.

11. The agent for reducing side effects according to claim 8, wherein the number of the small soft capsule preparation (A) is 1 or 2.

12. The agent for reducing side effects according to claim 10, wherein the small soft capsule preparation (A) has an outer diameter of from 0.1 mm to 2 mm.

13. The agent for reducing side effects according to claim 11, wherein the small soft capsule preparation (A) has an outer diameter of from 2 mm to 6 mm.

14. The agent for reducing side effects according to claim 7, wherein the oily solution base is middle chain fatty acid triglyceride.

15. The agent for reducing side effects according to claim 14, wherein the middle chain fatty acid triglyceride is tricaprylin.

16. The agent for reducing side effects according to claim 7, wherein the excipient is one or at least two substances selected from the group consisting of saccharides, corn starch, and crystalline cellulose.

17. The agent for reducing side effects according to claim 7, wherein the pharmaceutical composition (D-1) is in the form of granules.

18. The agent for reducing side effects according to claim 17, wherein the granules have an average particle size of from about 200 μm to about 600 μm .

19. The agent for reducing side effects according to claim 7, wherein the solid preparation is in the form of tablets.

20. The agent for reducing side effects according to claim 3, which is a single solid preparation which comprises at least one small soft capsule preparation (A) comprising ornoprostil and an oily solution base, and at least one small soft capsule preparation (C) comprising diclofenac or a salt thereof and an oily solution base.

21. The agent for reducing side effects according to claim 20, wherein the solid preparation is in the form of hard capsules.

22. The agent for reducing side effects according to claim 20, wherein the oily solution base in the soft capsule preparation (A) is tricaprylin, and the oily solution base in the soft capsule preparation (C) is middle chain fatty acid triglyceride.

23. The agent for reducing side effects according to claim 20, wherein the solid preparation is in the form of tablets.

24. The agent for reducing side effects according to claim 3, which is a single solid preparation which comprises a pharmaceutical composition (B) comprising ornoprostil and an oily solution base, and at least one small soft capsule preparation (C) comprising diclofenac or a salt thereof and an oily solution base.

25. The agent for reducing side effects according to claim 24, wherein the solid preparation is in the form of hard capsules.

26. The agent for reducing side effects according to claim 24, wherein the solid preparation is in the form of soft capsules.

27. The agent for reducing side effects according to claim 3, which is a single solid preparation which comprises at least one small soft capsule preparation (A) comprising ornoprostil and an oily solution base, and a pharmaceutical composition (D-2) comprising diclofenac or a salt thereof and an oily solution base.

28. The agent for reducing side effects according to claim 27, wherein the solid preparation is in the form of soft capsules.

29. The agent for reducing side effects according to claim 27, wherein the solid preparation is in the form of hard capsules.

30. The agent for reducing side effects according to claim 3, which is a soft capsule preparation wherein a pharmaceutical composition (B) comprising the ornoprostil and an oily solution base is coated with a soft capsule coat comprising the diclofenac or a salt thereof.

31. The agent for reducing side effects according to claim 1, which is a soft capsule preparation wherein a pharmaceutical composition (D-2) comprising the diclofenac or a salt thereof and an oily solution base is coated with a soft capsule coat comprising the ornoprostil.

32. A side effect-reducing hard capsule agent for reducing digestive disorders of diclofenac or a salt thereof, which is a hard capsule preparation which comprises at least one small soft capsule preparation (A-1) comprising ornoprostil and from 40 to 95% by weight of an oily solution base, and a pharmaceutical preparation (D-3) comprising diclofenac or a salt thereof and from 20 to 95% by weight of an excipient.

33. The hard capsule agent for reducing side effects according to claim 32, wherein the oily solution base is tricaprylin, and the excipient is one or at least two substances selected from the group consisting of saccharides, corn starch, and crystalline cellulose.